

VIA FEDERAL EXPRESS

Food and Drug Administration 555 Winderley Pl., Ste. 200 Maitland, Fl 32751

WARNING LETTER

FLA-01-62

June 20, 2001

Mr. Fu Chung Owner, Chung Farming 5900 Hoffner Avenue Orlando, Florida 32822

Dear Mr. Chung:

The Food and Drug Administration inspected your sprout production facility at the above address on May 30, 2001. Our inspection found that you have failed to adopt effective preventive controls to reduce the risk of raw sprouts becoming a vehicle for foodborne illness and to ensure that your sprouts are not adulterated under the provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our inspection found that your sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted by your sprouting facility. For example, at the time of our inspection in May, your firm had not conducted any microbial testing of spent irrigation water and no sampling method or plan for testing of spent irrigation water had been established. The seeds used for sprout production are washed in city water, which is also not tested for microbial contaminants, containers used for storing finished sprouts have holes in the bottom and are in direct contact with unsanitary

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surfaces, and the finished sprouts stored in a walk-in cooler are covered with a dirty blanket. Our inspection also disclosed garbage being stored adjacent to the building within a few feet of the outdoor packing and storage area.

We may take further action if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as recent test results for spent irrigation water, a method/plan for testing spent irrigation water and any other documentation that you have corrected the deficiencies noted in this letter. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. You can find this Act and guidelines for the production and testing of sprout products through links in FDA's home page at www.fda.gov.

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Please send your reply to the Food and Drug Administration, Attention: Martin E. Katz, Compliance Officer, 555 Winderley Place, Ste. 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Katz at (407) 475-4729.

Sincerely,

Emma R. Singleton
Director, Florida District